UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ALLEN LEFAIVRE, individually and on behalf of all others similarly situated,	)	
Plaintiff,	)	
vs.	)	**Case No. 4:09CV00588SNLJ**
KV PHARMACEUTICAL CO, ET. AL.,	)	
Defendant.	)	

MEMORANDUM

Plaintiff has filed this potential class action suit alleging damages arising from his purchases of a hypertension medication called Metoprolol Succinate ER. Plaintiff alleges that the drug's manufacturer breached its implied warranty of merchantability and violated the Missouri Merchantability Practices Act (MMPA), Sec. 407.010 RSMo, et seq., by failing to manufacture the medication in accordance with federal regulations. The defendant contends that the claims are essentially claims for violation of the federal regulations themselves and that there is no private cause of action for such claims. This matter is before the Court on defendant's motion to dismiss (#25), filed July 29, 2009. Responsive pleadings have been filed and the matter is now ripe for disposition.

I. Legal Standard

The purpose of a Rule 12(b)(6) motion to dismiss is to test the legal sufficiency of a complaint so as to eliminate those actions "which are fatally flawed in their legal premises and

designed to fail, thereby sparing litigants the burden of unnecessary pretrial and trial activity." Young v. City of St. Charles, 244 F.3d. 623, 627 (8th Cir. 2001) (*quoting* Neitzke v. Williams, 490 U.S. 319, 326-27 (1989)). A complaint must be dismissed for failure to state a claim upon which relief can be granted if it does not plead "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007) (abrogating the prior "no set of facts" standard set forth in Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). Courts "do not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. A complaint must set forth factual allegations sufficient to "raise a right to relief above the speculative level." Id. at 555. With these standards in mind, the Court turns to an examination of the plaintiff's complaint.

II. Statement of the Case

The facts of the case as alleged in plaintiff's complaint are as follows: KV Pharmaceuticals Company (KV) manufactures, markets, and distributes a hypertension medication called Metoprolol Succinate ER throughout the United States. The medication is manufactured in and distributed from Missouri. Plaintiff Allen Lefaivre, a resident of Rhode Island, had a prescription for this medication and purchased it on several occasions at retail pharmacies in Rhode Island.

On March 2, 2009, the Food & Drug Administration (FDA) filed a complaint against KV alleging that the company had failed to manufacture the medication in accordance with the standards promulgated by the FDA under certain provisions of Chapter V of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 351(a)(2)(B). Four days later, on March 6, 2009, the FDA and KV jointly filed a Consent Decree of Permanent Injunction settling the FDA's case

against KV with KV neither admitting nor denying the claims made by the FDA in its original complaint. Consent Decree of Permanent Injunction at 2, United States v. KV Pharm. Co., No. 4:09CV00333RWS (E.D. Mo. Mar. 6, 2009).

As a part of that Consent Decree, KV stipulated that it had sold drugs that were "adulterated" within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the drugs were manufactured, processed, packed, labeled, held, and distributed in violation of the FDA's current good manufacturing practice (CGMP) requirements. Consent Decree at 2,5. KV agreed that it had not utilized proper quality control procedures while manufacturing the medication. Consent Decree at 5. KV further stipulated that some of the medication sold to retail pharamacies had been misbranded in violation of federal regulations. Consent Decree at 3. Finally, KV agreed to destroy its remaining stock of "adulterated" drugs and issue a recall for all stocks of the medication sold to retailers between May 2008 and February 3, 2009. Consent Decree at 3-4. The recall notice was issued "at the retail level," meaning that KV instructed all retailers that had purchased the medication to return all unsold product to KV. Under the Consent Decree, KV was not required, nor did it, distribute its recall notice to individual purchasers of the subject medication.

III. DISCUSSION

Lefaivre has filed this lawsuit against KV in two counts alleging first, a breach of the implied warranty of merchantability, and second, violations of the Missouri Merchantability Practices Act (MMPA), Sec. 407.010 RSMo, *et seq*. Lefaivre argues that he has a right to maintain a private cause action for damages against KV because the medication KV

manufactured was "adulterated" under the FDCA. In that regard, 21 U.S.C. § 351(a)(2)(B), states in pertinent part:

> A drug or device shall be deemed to be adulterated—if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

The only injuries Lefaivre claims to have received because of the violation of the foregoing statute are his purchase costs for the medication. He does not allege any other injuries in connection with his purchase and/or consumption of the medication. He further claims that he (and other potential members of the class) are entitled to punitive damages and attorneys' fees due to KV's failure to comply with the CGMP requirements.

A. There is No Private Cause of Action for Enforcement of the FDCA

1. Established Precedent

For more than thirty years, federal courts at all levels have repeatedly held that there is no private cause of action for enforcement of the FDCA. See, e.g., In re Orthopedic Bone Screw Prods. Litig., 193 F.3d 781, 791 (3d Cir. 1999) ("[The FDCA] creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government." (*citing* 21 U.S.C. § 337(a)); Animal Legal Def. Fund Boston, Inc. v. Provimi Veal Corp., 626 F. Supp. 278, 283 (D. Mass. 1986) ("[Plaintiff's] complaint fails to state a claim on which relief can be granted because no private cause of action can be implied under the FDCA."); Pacific Trading Co. v. Wilson & Co., 547 F.2d 367, 370 (7th Cir. 1976) ("Thus, the statute does not provide a cause of action for

private parties suing for civil damages, and those allegations relating to the Federal Food, Drug and Cosmetic Act must ... be dismissed.").

The Supreme Court recently affirmed this long-standing precedent in Buckman Co. v. Plaintiff's Legal Comm'n, 531 U.S. 341 (2001), a case in which a private party brought suit against a medical device manufacturer on a common law fraud theory. Plaintiff's fraud theory was based on alleged misrepresentations to the FDA regarding the manufacturer's compliance with FDCA regulations. Instead of examining plaintiff's claim under a narrow express preemption provision applicable in medical devise cases, 21 U.S.C. § 360k(a), the Court decided the case under implied preemption principles. Id. at 348 n.2. The Court first observed that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." Id. at 347. The Court concluded that "given this analytical framework" and the fact that the state-law fraud claims at issue were based solely on FDCA disclosure requirements, those claims were "impliedly preempted by[] federal law." Id. at 348. The Court then added, albeit by way of footnote, that:

> The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).
> Id. at 349 n.4.

The preemptive effect under the FDCA, the Court noted, is not absolute, but to avoid being impliedly preempted, a claim must rely on "traditional state tort law which had predated the federal enactments in question." Buckman, 531 U.S. at 353. However, the state fraud claims

in Buckman, the Court held, "exist solely by virtue of the FDCA disclosure requirements," and "the existence of these federal regulations is a critical element in [the] case." Id. As such, the claims were disallowed.

At least one case since Buckman, Riley v. Cordis Corporation, 625 F.Supp.2d 769 (D.Minn. 2009), has explained the Buckman holdings in this way: If a plaintiff's claim is premised on conduct that would give rise to liability under state law—and would give rise to such liability "even if the FDCA had never been enacted"—the plaintiff may pursue the claim. Riley, 625 F. Supp. 2d at 777. However, "[i]f the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under Buckman." Id. (*citing* Buckman, 531 U.S. at 349 n.4).

In the case at hand, Lefaivre's first cause of action against KV is for breach of the implied warranty of merchantability, a claim that is based solely upon KV allegedly manufacturing and distributing "adulterated" prescription drugs in violation of the FDCA. In essence, Lefaivre is suing KV for violation of the FDCA's manufacturing and distribution requirements, and indeed, Lefaivre's complaint for the most part is a word for word recitation of the FDCA's violations listed in the Consent Decree. Despite the nomenclature, this is not an action based on traditional state tort law that predated the FDCA regulations, because it is not an action that is brought independently of the federal violations. It is instead an action that is wholly dependent upon the federal violations and would not exist absent the federal violations. Under these circumstances, the cause of action is impliedly preempted by federal law.

Lefaivre's second cause of action for violation of the Missouri Merchandising Practice Act fares no better. Specifically, Lefaivre alleges that KV engaged in an unlawful business practice by manufacturing, selling, and distributing medication that was adulterated under federal law and by failing to disclose to consumers that the medication was adulterated. This claim, too, is ultimately based on violations of the FDCA regulations and would not exist absent those violations. It is wholly dependent on the FDA's determination that the medication was adulterated. And though it is couched as an independent state law claim in form, it is not so in substance.

2. Effect of Wyeth v. Levine

Lefaivre's principal argument in opposition is that the Supreme Court case of Wyeth v. Levine, 555 U.S. __, 129 S.Ct. 1187 (2009), decided less than a year ago, effectively abrogates the long-standing precedent against private causes of action under the FDCA**.** Specifically, Lefaivre contends that the Supreme Court's rejection in Wyeth of *per se* conflict preemption of state lawsuits brought against drug manufacturers is an implicit authorization of private causes of action to enforce the FDCA. This Court disagrees.

In Wyeth, a patient brought an action in state court against the manufacturer of a nausea medication alleging that the drug manufacturer failed to include a warning advising medical staff against administering the drug directly into a patient's vein. The drug manufacturer argued that federal law preempted the state lawsuit on the ground that the FDA is the sole entity entrusted to regulate labeling for prescription drugs, and to allow state law claims that hold manufacturers liable for inadequate labels would contravene Congress's purpose in establishing the FDA. 129 S.Ct. at 1199. In its analysis, the Court first noted that Congressional intent indicates that the

FDA has traditionally regarded state law as a "complementary form of drug regulation" that "serve[s] a distinct compensatory function." 129 S.Ct. at 1202. The Court added that Congress's decision not to include an express preemption provision for prescription drugs in the face of such an extensive history of state law litigation over prescription medication "is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Id. at 1200. Accordingly, the Court held that private state-law tort suits are a permissible avenue for parties injured by prescription medications to pursue. Id. at 1202.

This conclusion, however, does not purport to affect the enduring precedent that there is no private stand-alone cause of action for violation of the FDCA. As noted, the case in Wyeth was predicated on a state law theory of liability for failure to warn that was wholly independent of the FDCA. In contrast, Lefaivre's claim here is based solely on the FDCA itself. Consistent with Buckman, Wyeth should be read only for the proposition that a plaintiff may assert a cause of action against a drug manufacturer if he or she has an independent state-law theory of liability (*i.e.*, if the cause of action would exist independently of the FDCA).

III. Conclusion

Because plaintiff Lefaivre's state law claims are based entirely on violations of FDCA regulations, and because enforcement of the FDCA is solely the province of the federal government, the claims are preempted and plaintiff has failed to state a cause of action. Accordingly, the case shall be dismissed.

Dated this 5th day of January, 2010.

UNITED STATES DISTRICT JUDGE